DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 21, 2015

Clinical Laserthermia Systems AB
% Mr. David Makanani
OMEDtech, LLC
1725 Signal Ridge Drive, Suite 150
Edmond, Oklahoma 73013

Re: K142216
Trade/Device Name: Tranberg^{cls} Thermal Therapy System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 20, 2015
Received: March 24, 2015

Dear Mr. Makanani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K142216

Device Name: Tranberg CLS Thermal Therapy System

Intended Use/Indications for Use:

"The Tranberg CLS Thermal Therapy System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery including: gastroenterology, general surgery, plastic surgery, genitourinary (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT) head and neck, orthopedics, ophthalmology, pulmonology, and thoracic surgery."

Prescription Use: X AND/OR Over-The-Counter Use: NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

510(k)

510(K) SUMMARY

Date	April 17, 2015
SUBMITTER:	Lars-Erik Eriksson, CEO Clinical Laserthermia Systems, AB Scheelevagen 2 Lund, Sweden 22381
CONTACT PERSON:	David Makanani, CEO OMEDtech, L.L.C. 1725 Signal Ridge Drive, Suite 150 Edmond, Oklahoma 73013 Tel: (405) 826-0713 Email: dmakanani@omedtech.com
DEVICE NAME:	
Classification	Class II
Trade Name	TRANBERG^{CLS}|Thermal Therapy System
Common Name	TRANBERG^{CLS}|Thermal Therapy System
Classification	21 CFR 878.4810
Product Code	GEX - Powered Laser Surgical Instrument
Review Panel	General and Plastic Surgery
PREDICATE DEVICE:	K092197: BioTex, Inc.; PhoTex30 Diode Laser.
INTENDED USE:	The Tranberg ^{CLS} Thermal Therapy System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery including: gastroenterology, general surgery, plastic surgery, genitourinary (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT) head and neck, orthopedics, ophthalmology, pulmonology, and thoracic surgery.

DEVICE DESCRIPTION:

The TRANBERG^{CLS}|Thermal Therapy System consists of three parts:

- TRANBERG^{CLS}|Mobile Laser

- TRANBERG[CLS]|Temperature Sensor
- Applicator Kit (The Applicator kit is not included)

The mobile laser unit is provided with a laser generator operating at the wavelength 1064 nm. The generated laser light is locally applied by means of a single use applicator kit through a less invasive surgical or percutaneous procedure. The energy within the laser light is absorbed by the tissue resulting in increased tissue temperature. Tissue heating and lesion formation is controlled by a tissue temperature feedback system integrated into the TRANBERG[CLS]|Thermal Therapy System.

For a detailed description of the function and the usage of the laser module and its accessories, view the IFU.

TECHNOLOGICAL CHARACTERISTIC AND SUBSTANTIAL EQUIVALENCE:
Substantial equivalence of the TRANBERG[CLS]|Thermal Therapy System is claimed to the PhoTex 30 Diode Laser Series, cleared under K092197.
The CLS device is verified and validated to have the same performance as the predicate device when used together with the Applicator kit cleared under K053087
The following table provides more detailed information regarding the basis for the determination of substantial equivalence:

Parameter		
Product name	TRANBERG[CLS]|Thermal Therapy System	PhoTex 30 Diode Laser Series
Manufacturer	Clinical LaserThermia Systems CLS, Sweden	BioTex, US

Intended use / Indications for use	"The Tranberg CLS Thermal Therapy System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery including: gastroenterology, general surgery, plastic surgery, genitourinary (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT) head and neck, orthopedics, ophthalmology, pulmonology, and thoracic surgery."	"The PhoTex3 Diode Laser Series is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery including: gastroenterology, general surgery, plastic surgery, genitourinary (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT) head and neck, orthopedics, ophthalmology, pulmonology, and thoracic surgery."
Device Regulatory Classification	FDA 878.4810	FDA 878.4810
Product code	GEX	GEX
Device class	2	2
510(k) No	To be obtained	K092197
Diode laser generator		
Wavelength	1064nm Adapted to indication for use of the laser applicator / hand piece	980nm, 810nm or 940 nm
Output power	1W - 25W at output port	3W – 30W at output port
Output power accuracy	+/- 10% of selected value	+/- 20% of selected value
Mode of operation	Continuous wave or controlled by tissue temperature monitored by a temperature sensor	Continuous wave (CW), pulsed, or external modulation modes.
Output power increments	1W	0.5 W
Cooling	TEC	TEC
Channel(s)	1	1
Output port	SMA 905	SMA 905
Aiming wavelength	635 nm	650 nm
Laser type IEC60825-1	Class IV	Class IV
General technical characteristics		
Power source	100-240 V AC / 50-60 Hz	100-240 V AC / 50-60 Hz
Operating temperature range	15ºC to 28ºC	10-35 ºC
Average dimensions	540, 450, 180mm (width, depth, height)	16.0"x12,5"x8,0" (406x318x203)
Weight	18 Kg	20 lbs (9,1kg)
Foot switch operation	On/Off	On/Off

Emergency switch	Yes	Yes
Key activation of laser output	Yes	Yes
Remote Interlock	Yes	Yes
Power ON/OFF Visual Indicator	Yes	Yes
Laser Emission Indicator	Yes	Yes
Internal Laser Power Monitor	Yes	Yes
Manual Reset	Yes	Yes
Fiber Insertion Interlock	Yes	Yes
Laser Emission Energy Monitoring	Yes	Yes
Audio Warning Signal Level	Fixed at HIGH	HIGH, MEDIUM, LOW, and OFF
Safety classification FDA	Class II	Class II
Pump for cooling liquid for applicator	Yes	Yes
Temperature sensors included	Yes	No
Applicator kit (Laser fiber and Trochar)		
Interface	Compatible with fiber optic delivery accessory with a standard SMA905 connector having a core fiber diameter of 400 or 600 microns and a numerical aperture of at least 0.37.	Compatible with fiber optic delivery accessory with a standard SMA905 connector having a core fiber diameter of 400 or 600 microns and a numerical aperture of at least 0.37.
Performance	The CLS device is verified and validated to have the same performance when used together with the Applicator kit cleared under K053087	The BioTex device is verified and validated together with the Applicator kit cleared under K053087

PERFORMANCE TESTING - (NON-CLINICAL) BENCH:

The TRANBERG^{CLS}|Thermal Therapy System has been determined through engineering bench testing to support substantial equivalence with this device and the predicates. This testing showed the TRANBERG^{CLS}|Thermal Therapy System to meet applicable ISO, IEC and FDA safety and performance standards,

Non-clinical bench performance testing completed:

- Engineering comparative temperature testing
- Engineering Verification and Validation Testing to the Product Requirement Specification

- Software testing
- Usability Engineering Testing - ISO 62366
- Electromagnetic Compatibility – IEC 60601-1-2 Collateral Standard
- Electrical Safety for Laser Equipment – IEC 60601-2-22 Particular Standard
- Medical Device Sterilization of Health Care Products – ISO 11135-1; Ethylene Oxide

PERFORMANCE TESTING – CLINICAL:

There are no clinical data submitted with this Notification.

CONCLUSION:

Based on the results of non-clinical testing, the TRANBERG^{CLS}|Thermal Therapy System performs safely, as intended, and the comparative discussion of intended use, principle of operation, and technological characteristics, it is determined that the TRANBERG^{CLS}|Thermal Therapy System is substantially equivalent to predicate devices.